PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BRUFEN® RETARD 800 mg sustained-release tablets

Ibuprofen

Sugar free.

Read all of this leaflet carefully before you start taking BRUFEN® RETARD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BRUFEN® RETARD has been prescribed for your personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BRUFEN® RETARD is and what it is used for
2. What you need to know before you take BRUFEN® RETARD
3. How to take BRUFEN® RETARD
4. Possible side effects
5. How to store BRUFEN® RETARD
6. Contents of the pack and other information.

1. What BRUFEN® RETARD is and what it is used for

BRUFEN® RETARD contains ibuprofen and belongs to a group of medicines called antirheumatics and anti-inflammatory medicines.

BRUFEN® RETARD is used to relieve pain and inflammation in conditions such as osteoarthritis,

rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

BRUFEN® RETARD can also be used to treat other painful conditions such as toothache, pain after operations, period pain and pain after childbirth.

2. What you need to know before you take BRUFEN® RETARD

Do not take BRUFEN® RETARD:

- If you are hypersensitive (allergic) to ibuprofen or any of the other ingredients of BRUFEN® RETARD (listed in section 6) or experienced worsening of asthma, itching or a runny nose after taking ibuprofen, aspirin or any other nonsteroidal anti-inflammatory medicines.
- If you currently have a peptic ulcer (ulcer in your stomach or duodenum).
- If you are in your third trimester of pregnancy.
- If you have or previously had bleeding in your stomach as a result of taking medicines.
- If you have or previously had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- If you suffer from severe heart problems.
- If you suffer from severe liver or severe kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist if you suffer from frequent headaches and regular take pain medicine to treat these headaches.

Take special care with BRUFEN® RETARD:

- If you are over the age of 65 years.
- If you have, or have you previously had, a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach.
- If you currently or previously suffered from:

  - ulcerative colitis (inflammatory bowel disease causing inflammation and ulcers in your digestive tract),
  - Crohn's disease (inflammatory bowel disease causing inflammation and pain in your stomach area, diarrhoea, fatigue and weight loss),
  - hiatus hernia (a tear in the muscle separating your stomach and lower chest),
  - gastroesophageal reflux disease (causing acid reflux),
  - angiodysplasia (abnormality in the blood vessels of the gastrointestinal tract).
- If you suffer from asthma or have ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers.
- If you have heart, kidney or liver problems.
- If you have high blood pressure.
- If you are dehydrated (e.g. when you have diarrhoea or are vomiting).
- If you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting your connective tissue).
- If you have been diagnosed with chicken pox or shingles.
- If you have been diagnosed with an infection. Tell your doctor immediately if your symptoms do not improve or worsen while taking BRUFEN® RETARD.
- If you have a tendency to bleed easily.

Stop taking BRUFEN® RETARD immediately and tell your doctor if you experience any unusual stomach symptoms, including dark stools which may be indicative of stomach bleeding.

Serious skin reactions have been reported in association with BRUFEN® RETARD treatment. You should stop taking BRUFEN® RETARDand seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction.

Children and adolescents

BRUFEN® RETARD is not recommended for use in children under 12 years of age.

Other medicines and BRUFEN® RETARD

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Medicines to lower your blood pressure.
- Beta-blockers (used to treat irregular heartbeat).
- Diuretics (“water tablets” used to lower blood pressure or reduce fluid build-up).
- Other anti-inflammatory medicine or aspirin.
- Corticosteroids (cortisone-like medicines, used to treat inflamed areas of your body).
- Medicines to prevent blood clots.
- Selective serotonin reuptake inhibitors (SSRI’s) (used to treat depression).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Colestyramine (used to treat high levels of lipid in your blood).
- Lithium (used to treat some types of depression).
- Methotrexate (used to treat rheumatoid arthritis).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Mifepristone (used to induce labour or for the medical termination of pregnancy).
- Quinolone antibiotics, such as ciprofloxacin, ofloxacin, moxifloxacin (used to treat certain infections).
- Sulfonylurea medicines, such as glimepiride or glipizide (used to treat high blood sugar).
- Tacrolimus (used to prevent organ rejection after a transplant).
- Zidovudine (used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome)).
- Aminoglycoside antibiotics, such as gentamicin, tobramycin, kanamycin, neomycin, streptomycin (used to treat certain infections).

- Ginkgo biloba (herbal medicine).
- Voriconazole or fluconazole (used to treat fungal infections).

BRUFEN® RETARD with food, drink and alcohol

The use of alcohol during treatment with BRUFEN® RETARD may worsen side effects, such as dizziness, drowsiness and stomach problems. Do not drive a vehicle or operate machines until you know how BRUFEN® RETARD affects you.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. BRUFEN® RETARD should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and using machines

BRUFEN® RETARD may cause side effects, such as dizziness, drowsiness, tiredness or visual impairment. Do not drive or operate machines until you know how BRUFEN® RETARD affects you.

3. How to take BRUFEN® RETARD

Do not share medicines prescribed for you with any other person.

Always take BRUFEN® RETARD exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of BRUFEN® RETARD is too strong or too weak, tell your doctor or pharmacist.

Adults and children over 12 years old:

The usual dose is 2 tablets taken once a day in the evening.

Your doctor may prescribe you 3 tablets taken in two divided doses.

Take the lowest effective dose for the shortest possible time.

Swallow the tablet with water.

You can take the tablets with or after food.

BRUFEN® RETARD should be swallowed whole and not chewed, broken, crushed or sucked.

Your doctor will tell you how long your treatment with BRUFEN® RETARD will last.

If you take more BRUFEN® RETARD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BRUFEN® RETARD

Take your BRUFEN® RETARD as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BRUFEN® RETARD can have side effects.

Not all side effects reported for BRUFEN® RETARD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BRUFEN® RETARD, please consult your health care provider for advice.

If any of the following happens, stop taking BRUFEN® RETARD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, angkles, facte, lips and mouth or throat, which may cause diffuculty in swallowing or breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BRUFEN® RETARD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- aseptic meningitis (causing severe headache, high temperature, neck stiffness and an intolerance to bright light),
- intestinal bleeding (pain in your stomach area, passing blood in your stools or vomiting blood, black tarry stools),
- liver disease or liver failure (stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick) of blood, yellowing of skin or eyes),
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis,
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea).
- kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you),
- tubulointerstitial nephritis (passing more or less urine than is normal for you, blood in your urine, dark urine, nausea, vomiting),
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back),
- pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath.
- heart failure (shortness of breath, fatigue and weakness, swelling of the legs, ankles and feet,

rapid or irregular heartbeat, persistent cough with white or pink phlegm),

- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- bleeding or bruising more easily than normal,
- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration),
- loss of vision, blurred or disturbed vision (visual impairment),
- difficulty in breathing, wheezing,
- gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling dizzy, nervous, drowsy,
- headache,
- indigestion, diarrhoea, nausea (feeling sick), vomiting (being sick), pain in your stomach area, flatulence, constipation,
- blood in your vomit or stools,
- rash,
- feeling tired.

Less frequent side effects:

- sneezing, blocked, itchy or runny nose (rhinitis),
- feeling anxious, depressed or confused,
- difficulty sleeping, sleepiness,
- tingling or numbness of your hands and feet (pins and needles),
- difficulty hearing, ringing in the ears,
- vertigo (sensation of spinning or swaying),
- high blood pressure,
- stomach discomfort, mouth sores,

- worsening of Chron's disease or colitis,
- abnormal liver function tests,
- skin sensitivity to light,

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BRUFEN® RETARD.

5. How to store BRUFEN® RETARD

- Store at or below 25 °C.
- Protect from light.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BRUFEN® RETARD contains

The active substance is ibuprofen.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, hypromellose, Opaspray White M-1-7111B (containing hypromellose and titanium dioxide (E171), povidone, stearic acid, talc, titanium dioxide and xhanthan gum.

What BRUFEN® RETARD looks like and contents of the pack

A white, pillow-shaped, film-coated tablet.

Cartons containing 60 tablets in blister strips.

Holder of certificate of registration

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